



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

AUG 18 2004

Ms. Heidi Horn  
Perrigo Company of South Carolina  
515 Eastern Avenue  
Allegan, Michigan 49010

Dear Ms. Horntri:

This is in response to your letter of August 6, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Complete** containing folic acid is using the claim "[M]ay help reduce their risk of having a baby with birth defects of the brain and spinal cord." This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between the folate and the risk of neural tube defects. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in the regulation above would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in the respective regulation subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Detroit District Office, Office of Compliance, HFR-CE740

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

AUG - 9 2004

## NOTIFICATION OF DIETARY SUPPLEMENT CLAIMS

<b>Manufacturer Name and Address:</b>  Perrigo Company of South Carolina 515 Eastern Avenue Allegan, MI 49010		
<b>Statement Text:</b>  Folic Acid Women who consume adequate amounts of this B vitamin, as part of a healthful diet before pregnancy, may help reduce their risk of having a baby with birth defects of the brain and spinal cord.		
<b>Dietary Ingredient:</b>  Folic Acid	<b>Dietary Supplement Name:</b>  Complete	
<b>Appears on the following label:</b>		
H-E-B®		

I hereby certify that the information presented and contained in this notice is complete and accurate.

I also certify that Perrigo Company has substantiation to verify that the statement is truthful and not misleading.

Heidi Horn August 5, 2004  
Signature/Date

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